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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/830,994 | 05/03/2001 | Kristiina Ylihonko | 1574/49884 | 7174 |

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EXAMINER

KERR, KATHLEEN M

ART UNIT PAPER NUMBER

1652

DATE MAILED: 10/24/2003

AS

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/830,994

Applicant(s)

YLIHONKO ET AL.

Examiner

Kathleen M Kerr

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 9-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-5 and 9-15 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Application Status

1. In response to the previous Office action, a written restriction requirement (Paper No. 8, mailed on June 2, 2003), Applicants filed an election and amendment received on August 11, 2003 (Paper No. 11). Said amendment amended Claims 2 and 3. Thus, Claims 1-5 and 9-15 are pending in the instant Office action. The instant Office action is a supplemental restriction requirement that better groups the instant claims. Said supplemental requirement is at the discretion of the Examiner (see M.P.E.P. § 802 and 37 C.F.R. § 1.142) and is deemed appropriate and necessary in view of the complex subject matter of the instant claims and the extensive searching required to identify prior art relating to the instant subject matter.

Restriction

2. Restriction is required under 35 U.S.C. § 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 C.F.R. § 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-3 and 9-15, drawn to the full gene cluster for aclacinomycin, SEQ ID NO:14, sequences related to the full-length, and a first method of use.

Group II, claim(s) 2, 3, 5, and 9-15, drawn to a part of the gene cluster for aclacinomycin that is the *sga1* gene found in plasmid Sg5 and a first method of use.



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Group III, claim(s) 2, 3, 5, and 9-15, drawn to a part of the gene cluster for aclacinomycin that is the sga2 gene found in plasmid Sg5 and a first method of use.

Group IV, claim(s) 2, 3, 5, and 9-15, drawn to a part of the gene cluster for aclacinomycin that is the sga3 gene found in plasmid Sg5 and a first method of use.

Group V, claim(s) 2, 3, 5, and 9-15, drawn to a part of the gene cluster for aclacinomycin that is the sga4 gene found in plasmid Sg5 and a first method of use.

Group VI, claim(s) 2-5 and 9-15, drawn to a part of the gene cluster for aclacinomycin that is the sga5 gene found in plasmids Sg4 and Sg5 and a first method of use.

Group VII, claim(s) 2-4 and 9-15, drawn to a part of the gene cluster for aclacinomycin that is the sga6 gene found in plasmid Sg4 and a first method of use.

Group VIII, claim(s) 2-4 and 9-15, drawn to a part of the gene cluster for aclacinomycin that is the sga7 gene found in plasmid Sg4 and a first method of use.

Group IX, claim(s) 2-4 and 9-15, drawn to a part of the gene cluster for aclacinomycin that is the sga8 gene found in plasmid Sg4 and a first method of use.

Group X, claim(s) 2-4 and 9-15, drawn to a part of the gene cluster for aclacinomycin that is the sga9 gene found in plasmid Sg4 and a first method of use.

Group XI, claim(s) 2-4 and 9-15, drawn to a part of the gene cluster for aclacinomycin that is the sga10 gene found in plasmid Sg4 and a first method of use.

Group XII, claim(s) 2-4 and 9-15, drawn to a part of the gene cluster for aclacinomycin that is the sga11 gene found in plasmid Sg4 and a first method of use.

Group XIII, claim(s) 2-4 and 9-15, drawn to a part of the gene cluster for aclacinomycin that is the sga12 gene found in plasmid Sg4 and a first method of use.

Group XIV, claim(s) 2-4 and 9-15, drawn to a part of the gene cluster for aclacinomycin that is the sga13 gene found in plasmid Sg4 and a first method of use.

3. The inventions listed as Groups I-XIV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group I requires a specific structure, SEQ ID NO:14, and function, anthracycline biosynthesis; both these features together denote the special technical feature of the first Group. Groups II-XIV are each drawn to a part of SEQ ID NO:14, said parts being interpreted from the specification to be the genes described in Table 1 on page 12. The structure of *sga5*, for example, is different from the structure of SEQ ID NO:14 in its entirety. Moreover, the function of *sga5*, which is to encode a dTDP-glucose 4,6-dehydratase, is different from the function of the entire gene cluster, which is to produce aclacinomycin. Thus, the special technical feature of Group I is not shared by any of Groups II-XIV.

Response to Traversal of Restriction Requirement

4. Applicant's election with traverse of Group I in Paper No. 11 is acknowledged. The traversal is on the ground(s) that the features of the two groups of claims are sufficiently related that they should be examined and allowed in a single application. This is not found persuasive because unity of invention guidelines must be followed, not necessarily an assessment of "sufficient relationship". Applicants also argue that unity guidelines have been violated because the methods are specially adapted to use the DNA. This argument is moot because the first technical feature, as claimed now after the amendment filed August 11, 2003, is considered a special technical feature and is herein grouped with the first method of using it.

Election

5. A telephone call was made to Herbert Cantor on October 22, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

Conclusion

6. A complete response to the instant Office action must include an election of invention to be examined.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

KMK

October 22, 2003

